MICRONIZED FREEZE-DRIED PARTICLES

Abstract Of The Disclosure

A process is provided for making dry, micronized particles of an agent, such as a drug. The method includes (a) dissolving a macromolecular material, preferably a polymer, in an effective amount of a solvent, to form a solution; (b) dissolving or dispersing the agent in the solution to form a mixture; (c) freezing the mixture; and (d) drying by vacuum the mixture to form solid particles of the agent dispersed in solid macromolecular material. The micronization in this process occurs directly in a macromolecular matrix and hardening of the particles of agent by solvent removal takes place by lyophilization of the bulk matrix, which stabilizes the drug particles during hardening and prevents coalesence, thereby resulting in smaller final drug particles. The method is particularly preferred for protein agents. The process can be used in conjunction with a standard microencapsulation technique, typically following separation of the agent from the macromolecular matrix. The process yields microparticles having a homogenous size distribution, preferably less than 2 μm, and more preferably less than 1 μm, in size. The microparticles have well defined, predictable properties, which is particularly critical in drug delivery applications.